Data Evaluation Report on the effects of saflufenacil on *Aphidius rhopalosiphi*

PMRA Submission Number: 2008-0431 **MRID#: 47523804**

PMRA# for DER: 1636082 **PMRA# for original study: 1634464**

Data requirement	**TGAI**
PMRA Data Code:	9.2.6
EPA DP Barcode:	349851
OECD Data Point:	IIA 8.8.1.1
EPA Guideline:	n/a
OPPTS Guideline:	n/a

Test material: **BAS 800 01 H** **Guarantee:** 70.0% BAS 800 H

Active ingredient: saflufenacil

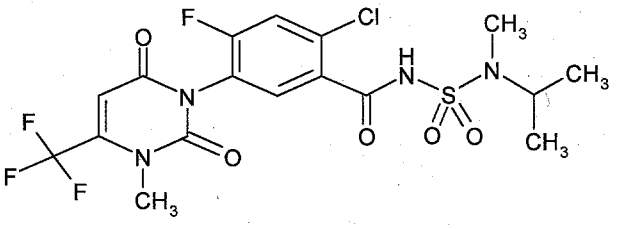
IUPAC: N'-[2-chloro-4-fluoro-5-(3-methyl-2,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2H)-pyrimidinyl)benzoyl]-N-isopropyl-N-methylsulfamide

CAS name: 2-chloro-5[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2H)-pyrimidinyl]-4-fluoro-N-[(methyl(1-methylethyl)amino]sulfonyl]-benzamide

CAS No.: 372137-35-4

Synonyms: BAS 800 H

Structural formula:



Primary Reviewer: Janine Glaser (1009) **Date:** 2008-Sep-17
Canada-HC-PMRA-EAD

Secondary Reviewers: Anita Pease **Date:** 2009-Jun-09
United States-EPA-OPP-EFED-ERB4

Farzad Jahromi **Date:** 2008-Dec-17
Australia-DEWHA-CAS

PMRA Company Code	BAZ
PMRA Active Code	SFF (saflufenacil)
PMRA Use Site Category	13, 14
EPA PC Code	118203 (saflufenacil)

CITATION: Stevens J. 2008. A rate-response laboratory test to determine the effects of BAS 800 01 H on the parasitic wasp, *Aphidius rhopalosiphi* (Hymenoptera, Braconidae). 2008-Aug-26. BASF-2008/1035600; MRID-47523804; PMRA-1634464.

EXECUTIVE SUMMARY

The effects of the water-dispersible granule BAS 800 01 H (70% saflufenacil) on mortality of the parasitic wasp (*Aphidius rhopalosiphi*) were determined. Ten wasp imagines per replicate were exposed to dried residues on glass plates at rates of 56, 113, 225, 450, and 900g product/ha (39.2, 79.1, 157.5, 315, and 630g saflufenacil/ha) over a period of 48 hours. In addition, purified water as control and a toxic reference (dimethoate, 400 g/l) at 0.10 mL product/ha were tested. The test was conducted with 4 replicates per rate. Mortality was used to determine the endpoint. The 48h LR50 value was 810g product/ha (567g saflufenacil/ha).

This study is classified as **FULLY RELIABLE** to PMRA and APVMA and **SUPPLEMENTAL** to EPA (data are not required for registration in the USA). The results are suitable for use in regulatory risk assessment.

Results Synopsis

Test organism: *Aphidius rhopalosiphi* imagines
48h LR50: 810g product/ha (567g saflufenacil/ha)

% deviation from control
for reproductive endpoint: not determined

I. MATERIALS AND METHODS

Guideline: IOBC/OILB 2000 (Mead-Briggs et al., pp 13-25)
GLP: yes (certified laboratory)
Testing facility: Mambo-Tox Ltd, Chilworth Science Park, Southampton, UK
Dates of work: 2008-Jun-25 to 2008-Jul-4
Deviations: Test was performed without the reproduction phase.

A. Test substance

Name: BAS 800 01 H
Type of formulation: WG (water dispersible granule)
Batch No.: 1641-87
Expiry date: 2009 Sep 12
Content: 68.8% saflufenacil (analysed)

Table 1: Physical and chemical properties of active substance

Parameter	Value
Water solubility	pH 4 0.0014 g/100 mL pH 5 0.0025 g/100 mL pH 7 0.21 g/100 mL pH 9 not determined due to degradation

Vapour pressure	4.5×10^{-15} Pa at 20°C 2.0×10^{-14} Pa at 25°C		
UV absorption	pH λ_{max} (nm) ε (L/mol-cm)	1.12 271.8 9539	6.94 271.4 9708
pK_a	4.41		
log K_{ow}	2.6		

B. Toxic reference

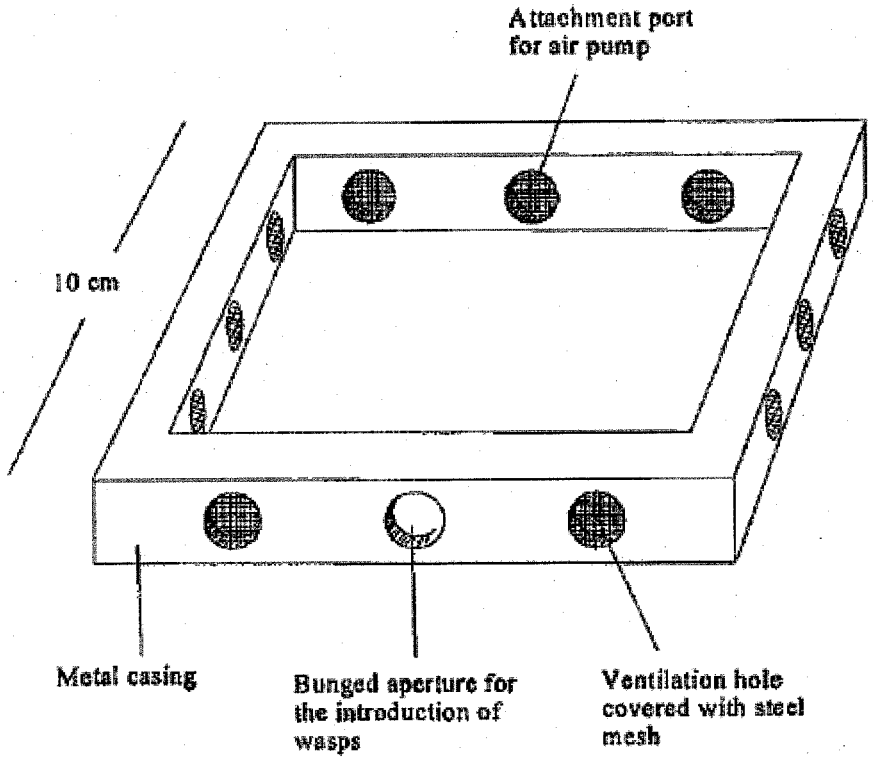
Identification code: BAS 152 11 I
Active ingredient: Dimethoate
Analysed content: 395.9 g/l
Type of formulation: emulsifiable concentrate

C. Test organisms

Species: *Aphidius rhopalosiphi*
Common name: parasitic wasp
Age: imagines, <48 hours after emergence
Source: Katz Biotech AG, Baruth, Germany;
formerly P.K Nützlingszuchten, Welzheim, Germany

D. Design of biological test

Ten imagines were exposed to dried residues of BAS 800 01 H in a standard laboratory test in a 2-dimensional test system on glass plates over a period of 48 hours. The test item was applied at rates of 56, 113, 225, 450, and 900g product/ha (39.2, 79.1, 157.5, 315, and 630g saflufenacil/ha) with a water volume of 200 L/ha. In addition, purified water as control and a toxic reference (dimethoate, 400 g/l) at 0.10 mL product/ha were tested. One unit consisted of two treated glass plates (100×100mm) fitted to the top and bottom of a square metal frame (inner size 95×95×18mm) with three ventilation holes on each side. This set-up served as one exposure unit (replicate) in which 10 imagines were released at test start. The test was conducted with 4 replicates per rate. The food provided to the wasps was a piece of cotton wool soaked in 1:3 v/v mixture of honey and water. The cotton wool would have been remoistened daily; however, this was not specified in the original report.



D. Observations and measurements

Mortality (including moribund insects) was assessed at 2, 24, and 48 hours after introduction to test units. Affected insects (upright, attempting to walk but with reduced coordination or inactive) were also recorded at the same times. Light intensity was measured once at the beginning of the test. The temperature and relative humidity were measured each hour.

II. RESULTS

A. Physical and chemical parameters

Test temperature:	19-20°C
Relative air humidity:	63-85%
Photoperiod:	16 hours light/ 8 hours dark
Light intensity:	2010 lux

B. Verification of the application volume

The sprayer was calibrated in advance of treatment by weighing spray deposits until two consecutive applications had delivered 200 L/ha (2 mg deposit/cm^2).

C. Biological findings

Effects are listed as follows:

Table 2: Effects of BAS 800 01 H on *Aphidius rhopalosiphi* after 48 hours

Treatment	g product/ha	% affected	% mean mortality (uncorr.)	% mean mortality (corr.)
control	0	0.0	2.5	—
Test item	56	0.0	5.0	2.6
Test item	113	0.0	2.5	0.0
Test item	225	0.0	2.5	0.0
Test item	450	0.0	10.0	7.7
Test item	900	7.5	72.5*	71.8
Reference item	0.10 mL product/ha	0.0	100.0*	100.0

*statistically different to the control (Fisher's Exact Test, α=0.05)

Statistical analysis of trial results to detect significant differences was not verified by the Regulatory Authority since they are not used to determine the key regulatory endpoint.

D. Test with toxic reference substance

The reference item was dimethoate (395.9 g/l analysed) and was applied under the same test conditions at 0.1 mL/ha (4 replicates). The cumulative mean mortality of mites exposed to the reference item after 48 hours was within the expected limits of 50-100% (M_{corr} = 100.0%). Thus, the test with toxic reference substance demonstrates the sensitivity of the test system.

E. Validity criteria

The validity criterion of 48h control mortality ≤13% is fulfilled. The validity criterion regarding the performance of the toxic reference is fulfilled.

F. Biological endpoints derived

From the results presented above, the following biological endpoint was derived by the study author:

7d LR50: 810g product/ha (567g saflufenacil/ha)
95% CI: 460-7566g product/ha (322-5296g saflufenacil/ha)
Analysis: Probit regression

Regression coefficent: 2.568 (SE 0.127)
Intercept of probit line: -7.468 (SE 0.340)
Goodness of fit (χ^2): 986 with 18 d.f. ($p<0.001$)

The derived endpoint was verified by the Regulatory Authority by plotting the probit of replicate corrected mortality versus log concentration in SigmaPlot; therefore, the endpoint derived from the study author is acceptable and was retained.

Regulatory Authority analyses:

Probit of corrected replicate mortality versus log concentration
$y = 0.2600 + 1.6317x$ (r^2 0.55)
LR50 803g product/ha

Probit of corrected mean mortality versus log concentration
Forced through origin
$y = -97.5785 + 48.4650x$ (r^2 0.55)
LR50 131g product/ha

III. STUDY DEFICIENCIES

Effects on reproduction were not determined. However, the Regulatory Authority accepts the deviation on the basis that a Tier 1 risk assessment indicates that there are no concerns about the use of saflufenacil affecting parasitic arthropod species (in- or off-field). The in-field RQ values do not exceed the level of concern (LOC 2.0).

Table 3: Tier 1 risk assessment of water-dispersible granule BAS 800 01 H (70% saflufenacil) on *Aphidius rhopalosiphi*

Risk assessment parameter	Canada	USA	Australia
EEC (g saflufenacil/ha)	100	400	3×24 =72
LR50 (g saflufenacil/ha)	567	567	567
RQ (EEC / LR50)	0.18	0.71	0.13

V. CONCLUSIONS

This study is classified as **FULLY RELIABLE** to PMRA and APVMA and **SUPPLEMENTAL** to EPA (data are not required for registration in the USA). The study appears to have been well conducted and reported. The results are suitable for use in regulatory risk assessment. The 48h LR50 value was 810g product/ha (567g saflufenacil/ha).